In the United States Court of Federal Claims

FOR PUBLICATION

No. 16-633V
(Filed: October 2, 2023[1])
Corrected on October 2, 2023

MELISSA LARSON,	)
Petitioner,	)
v.	)
SECRETARY OF HEALTH AND HUMAN SERVICES,	)
Respondent.	)

John F. McHugh, Law Office of John McHugh, New York, NY, for petitioner.

Alexa Roggenkamp, Trial Attorney, Torts Branch, Civil Division, U.S. Department of Justice, Washington, DC, for respondent. With her on the briefs were *Brian M. Boynton*, Principal Deputy Assistant Attorney General, and *C. Salvatore D'Alessio*, Director, *Heather L. Pearlman*, Deputy Director, and *Alexis B. Babcock*, Assistant Director, Torts Branch, Civil Division, U.S. Department of Justice, Washington, DC.

OPINION AND ORDER

BONILLA, Judge.

On May 27, 2016, Melissa Larson filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et seq*., initially claiming she developed fibromyalgia after receiving an influenza vaccine as a condition of her employment as a healthcare worker. She subsequently claimed the vaccine caused her to develop Guillain-Barré Syndrome (GBS), relegating her asserted fibromyalgia diagnosis to the sequela of GBS. On April 28, 2023, the

[1] This decision was initially filed under seal on September 15, 2023, in accordance with Rule 18(b) of the Vaccine Rules of the United States Court of Federal Claims, to allow the parties to propose redactions based upon privacy concerns. No proposed redactions were filed.

special master issued a decision denying entitlement, finding petitioner failed to adequately demonstrate she suffered from GBS. Petitioner filed a timely motion for review. For the reasons discussed herein, the Court finds the special master's decision was not arbitrary, capricious, an abuse of discretion, or otherwise contrary to law. Accordingly, the motion for review is DENIED and the decision below is SUSTAINED.

BACKGROUND

Petitioner received a seasonal influenza vaccination on November 6, 2013. According to her hearing testimony, annual flu shots were a condition of petitioner's employment as a respiratory therapist. Six weeks later, on December 17, 2013, petitioner presented at the emergency room with severe lower back pain. She was prescribed a muscle relaxant and pain medications and discharged the same day with the following diagnosis: "Sprain of lumbosacral (joint) (ligament)." *See* ECF 7-3 at 29. Between December 18-24, 2013, petitioner had several follow-up appointments with her primary care doctor. Initially attributing petitioner's back pain to musculoskeletal sprain, a magnetic resonance imaging (MRI) scan revealed an angular tear/herniated disc and a slight vertebra misalignment. Petitioner was administered and prescribed additional medications for her back pain and referred to a neurosurgeon.

On December 27, 2013, petitioner reported new symptoms to a neurologist, including numbness, facial drooping, shortness of breath, difficulty swallowing, and increasing weakness. In their evaluation, the neurologist noted: "My concern at this point is that the patient has Guillain-Barr[é] [S]yndrome. This could be a reaction to the flu shot that she received." ECF 7-5 at 6. This was the first time a physician raised a possible GBS diagnosis. Petitioner was immediately transported to the emergency room and referred to the hospital's Neuro Intensive Care Unit (Neuro-ICU) for monitoring and a series of additional tests, including a spinal tap. Analysis of her cerebrospinal fluid (CSF) showed a slightly elevated protein level. Despite the concern of possible GBS, petitioner was not treated for this condition and was discharged four days later after her symptoms largely subsided.[2] Nevertheless, petitioner's December 31, 2013 discharge diagnoses included "[g]eneralized weakness, possible Guillain-Barr[é] [S]yndrome." ECF 8-1 at 69.

[2] Petitioner was not prescribed the generally accepted treatment for GBS: rapid immunomodulatory therapies (i.e., Intravenous Immunoglobulin (IVIG) or Plasmapheresis). *See* https://www.mayoclinic.org/diseases-conditions/guillain-barre-syndrome/diagnosis-treatment/drc-20363006 (last visited Sept. 13, 2023). Instead, in addition to a prescribed muscle relaxant and pain medications, she engaged in outpatient physical therapy. During oral argument, counsel explained that while in transport from Aurora Lakeland Medical Center in Elkhorn, Wisconsin, to Aurora St. Luke's Medical Center in Milwaukee, Wisconsin (i.e., an estimated distance of 41.4 miles), petitioner's breathing stabilized and her most concerning symptoms plateaued such that a "wait and see" approach was adopted by hospital staff at Aurora St. Luke's Medical Center.

Throughout 2014, petitioner continued to seek medical treatment from a series of neurologists and other medical specialists for her recurring and evolving symptoms (e.g., lower back pain, "pins and needles" sensations, weakness, fatigue). Initially, the physicians were circumspect, leaving open the possibility petitioner had suffered a bout of GBS. In February 2014, for example, a cardiologist noted their impressions as follows: "Atypical chest pain and tachycardia in the setting of a recent viral syndrome/Guillian [sic] Barr[é]. The possibility of myopericarditis needs to be considered as does autonomic dysfunction in this clinical setting." ECF 7-3 at 106; *but compare* ECF 7-5 at 16–17 (January 23, 2014 follow-up GBS visit: "wait a week and watch for improvement" treatment plan) *with id.* at 11 (January 13, 2014 medical assessment: "very unusual" for petitioner's current condition to align with GBS diagnosis). When readmitted to the Neuro-ICU for "generalized progressive weakness" on March 14, 2014, a treating physician noted petitioner's "recent history of GBS diagnosis which was named on clinical exam and history with concern for respiratory compromise." ECF 8-5 at 6. However, the neurologist expressed doubts about the clinical diagnosis, explaining: "She may have had GBS in [sic] back in December given the characteristics and evolution of her symptoms, nevertheless I don't believe this is the case at this time."[3] *Id.* at 4–5. Thereafter, the neurologists who examined petitioner grew increasingly suspect of GBS and, instead, considered fibromyalgia as a more likely diagnosis.[4]

In May 2014, a neurologist documented his misgivings:

> I spent a lot of time explaining to the patient and her husband that she does not have Guillain-Barr[é] or Guillain-Barr[é]-like disease. If there was such a disease, it would have started within 10 days of vaccination because that is when the antibodies are produced. Her EMG study would have been abnormal. She would have lost her reflexes, so there is no evidence that she had that. Therefore, I cannot tell them why she had this disease with paralysis of the arms and legs.

ECF 19-1 at 5. Over the next several months, petitioner was diagnosed with subjective generalized muscle weakness and the treating neurologists continued questioning the basis for any GBS diagnosis. *See, e.g.*, ECF 9-1 at 24, 68.

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[3] During her March 2014 hospital stay, petitioner underwent a second spinal tap and an electromyography and nerve condition study (EMG/NCS); her CSF again measured a slightly elevated protein level and her EMG/NCS results were normal. Petitioner's post-March 2014 CSF studies were normal.

[4] Petitioner's late-2013/early-2014 application for worker's compensation based upon her alleged vaccine-caused injury was denied on March 31, 2014. The neurologist who reviewed petitioner's claim opined: "At this time, no clear diagnosis can be made of Guillain-Barr[é] [S]yndrome." ECF 95-7 at 54.

In October 2014, petitioner followed up with a neurologist who diagnosed her as suffering from "Fibromyalgia with widespread pain, tender points, sleep disturbance, and cognitive [symptoms] . . . ." ECF 9-2 at 57 (emphasis omitted). The neurologist questioned the prior GBS diagnosis, noting it lacked any "objective evidence." *Id.* at 51. Thereafter, in November and December 2014, petitioner consulted various medical professionals who consistently echoed the fibromyalgia diagnosis. *See, e.g.*, ECF 9-3 at 17 (repeated fibromyalgia assessment); ECF 9-8 at 58 (chronic pain and fatigue are "likely due to fibromyalgia"). Petitioner was eventually treated for fibromyalgia and returned to work in April 2016.

DISCUSSION

I. Standard of Review

In reviewing a Vaccine Act decision, this Court may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
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> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). The Federal Circuit clarified the applicable standards of review as follows: findings of fact are reviewed for arbitrariness or capriciousness; discretionary rulings are reviewed for abuse of discretion; and legal conclusions are reviewed *de novo*. *Turner v. Sec'y of Health & Hum. Servs.*, 268 F.3d 1334, 1337 (Fed. Cir. 2001) (citations omitted).

II. GBS-Based Claim

Petitioner claims her seasonal flu vaccine caused her to develop GBS.[5] As a

[5] GBS was added to the Vaccine Injury Table effective March 21, 2017. *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 42 Fed. Reg. 6294-01, 6295 (Jan. 19, 2017) (codified at 42 C.F.R. § 100.3(a)(XIV)(D)), as amended, 82 Fed. Reg. 11321-01, 11321 (Feb. 22, 2017) ("This document announces that the effective date is delayed until March 21, 2017."); *but cf. Wyatt v. Sec'y of Health & Hum. Servs.*, 825 F. App'x 880, 884 n.2 (Fed. Cir. 2020) ("GBS was added to the vaccine table in December 2017."). However, the Vaccine Act specifies the version of the Table in existence at the time a petition is filed controls. 42 U.S.C. § 300aa-14(c)(4) ("Any modification . . . of

threshold matter, the special master determined petitioner did not demonstrate she suffered from GBS, citing her clinical presentation, CSF and EMG/NCS results, and her treating physicians' medical assessments and prescribed treatments. In particular, the special master relied on the real-time, documented opinions of petitioner's later-treating physicians who, as noted *supra*, were increasingly suspect of the preliminary (working) GBS diagnosis. Petitioner argues the special master erred because "[t]he full medical record is fully consistent with a GBS diagnosis and nothing else." ECF 111 at 9. The Court disagrees.

Petitioner bears the burden to show by preponderant evidence a medically-recognized injury. *See Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010) (appropriate for special master to first determine which injury was supported by evidence before analyzing causation). "[I]f the existence and nature of the injury itself is in dispute, it is the special master's duty to first determine which injury was best supported by the evidence presented in the record . . . ." *Lombardi v. Sec'y of Health & Hum. Servs.*, 656 F.3d 1343, 1352 (Fed. Cir. 2011) (identification of petitioner's injury is a prerequisite to causation analysis). Moreover, as explained by the Federal Circuit:

> If a special master can determine that a petitioner did not suffer the injury that she claims was caused by the vaccine, there is no reason why the special master should be required to undertake and answer the separate (and frequently more difficult) question whether there is a medical theory, supported by "reputable medical or scientific explanation," by which a vaccine can cause the kind of injury that the petitioner claims to have suffered.

Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012) (quoting *Althen*, 418 F.3d at 1278).

In this case, the special master made a series of factual findings based upon a thoughtful and thorough examination of petitioner's extensive medical records (testing and treatment), the medical expert reports and live testimony, the medical literature, and petitioner's declaration and hearing testimony. Addressing petitioner's clinical presentation, the special master cited the following disconnects with a typical GBS diagnosis: petitioner's retention (and exaggeration) of reflexes; the non-monophasic nature of petitioner's reported symptoms; the transient (or inconsistent) facial diplegia reportedly experienced; and petitioner's documented

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the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation."). Because the petition in this case was filed in May 2016, the special master properly assessed this matter as an off-Table injury. *See Figueroa v. Sec'y of Health & Hum. Servs.*, 715 F.3d 1314, 1315 (Fed. Cir. 2013) (citing *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). Viewed in light of petitioner's failure to sufficiently demonstrate she suffered from GBS, discussed *infra*, this issue is largely academic.

recovery without receiving the primary (and generally accepted) treatments for GBS (i.e., immunotherapy). As with petitioner's clinical presentation, the special master found her normal EMG/NCS similarly inconsistent with a GBS diagnosis. The special master further surmised the slight elevation in protein in petitioner's CSF measured following her December 27, 2013 and March 14, 2014 spinal taps–despite the reported severity of her symptoms–was logically attributable to her recently diagnosed angular tear/herniated disc.[6]

Of particular significance, petitioner never underwent immunotherapies–the generally accepted treatment for GBS.[7] Instead, nearly a year later, she was treated for fibromyalgia, from which she recovered sufficiently to return to work in April 2016. Related to this issue, the special master reasonably credited petitioner's later-treating physicians, primarily neurologists, who opined the preliminary (working) GBS diagnosis was unsupported. Considering the potential life-threatening (but curable) nature of GBS, it was perhaps prudent for petitioner's initial treating physicians–particularly those in the hospital's emergency room–to consider the rare disease as part of their working diagnosis.[8] With the benefit of more medical data and hindsight, however, petitioner's treating physicians increasingly disfavored a GBS diagnosis. Although petitioner's symptoms subsided prior to these later medical assessments, they did so without the benefit of GBS-targeted treatment.

Taking the complete record into account, the special master aptly summarized the remote possibility petitioner suffered from GBS:

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[6] Notably, petitioner's treatment plan overlapped with measures generally prescribed for annular disc tears and herniations. *See* https://www.ncbi.nlm.nih.gov/books/NBK459235/ ("Treatment options for disc protrusion or herniation including conservative measures of nonsteroidal anti-inflammatory medications, physical therapy, and local injections.") (last visited Sept. 15, 2023).

[7] Given the autoimmune nature of Guillain-Barré syndrome, its acute phase is typically treated with immunotherapy, such as plasma exchange to remove antibodies from the blood or intravenous immunoglobulin. *See* https://www.who.int/news-room/fact-sheets/detail/guillain-barr%C3%A9syndrome#:~:text=There%20is%20no%20known%20cure,the%20blood%20or%20intravenous%20immunoglobulin (last visited Sept. 15, 2023).

[8] Both the World Health Organization and the Mayo Clinic highlight the rarity and potential life-threatening nature of GBS. *See* https://www.who.int/news-room/fact-sheets/detail/guillain-barr%C3%A9-syndrome#:~:text=Key%20facts,cases%20of%20Guillain%2DBarr%C3%A9%20syndrome (last visited Sept. 12, 2023); https://www.mayoclinic.org/diseases-conditions/guillain-barre-syndrome/symptoms-causes/syc-20362793 (last visited Sept. 12, 2023).

> Ultimately, if GBS was Petitioner's correct diagnosis, that would mean she is 1) among the approximately 10% of patients who do not experience diminished reflexes; 2) among the 2-5% of patients who do not have a monophasic course; 3) among the 4% of GBS patients who recovered without treatment; and 4) among the approximately 1% of patients with normal EMG results. While the co-occurrence of all these clinical features is possible, I do not find it is more likely than not. Viewing the medical record as a whole in light of the expert testimony and medical literature, I find that Petitioner has not provided preponderant evidence that she had GBS.

ECF 110 at 31–32 (internal citations omitted). Put simply, *possible* does not satisfy the required standard of proof: *reasonably probable*. *See Howard v. United States*, No. 16-1592, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("The standard for medical proof is preponderance–not plausibility. The statute is clear in this regard.") (citing 42 U.S.C. § 300aa-13(a)(1)(A)). The Court therefore declines petitioner's invitation to reassess her medical records and expert testimony. *See Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) ("We do not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses–these are matters within the purview of the fact finder.") (citing cases).

At bottom, the special master's factual determination that petitioner failed to meet her burden of demonstrating by preponderant evidence that she suffered from GBS is supported by the record presented. As such, there is no basis in fact or law for this Court to disturb that finding. In the absence of the claimed disease, there is no viable off-Table injury to assess.

III. Fibromyalgia-Based Claim

Given the evolution of petitioner's claim, one final issue merits discussion. When petitioner filed this action in May 2016–2.5 years after receiving the flu shot at issue and one month after returning to work–she referenced GBS as the initial "impression" and "concern" upon presentation at the emergency room; however, petitioner's claim was based on her "ultimate diagnos[is]" of fibromyalgia. *Compare* ECF 1 ¶ 5 (reference to GBS) *with id.* ¶ 10 (reference to fibromyalgia); *see id.* ¶ 12 ("Petitioner contends that she suffered Fibromyalgia which was caused-in-fact by the vaccine of November 6, 2013.") (citing 42 U.S.C. § 11(c)(1)(C)(ii)(I)). As noted by the special master at the outset of her opinion, petitioner thereafter shifted her theory of recovery from fibromyalgia to GBS without formally amending her petition. *See* ECF 110 at 1–2. This change was expressly confirmed in the course of the November 8, 2021 virtual hearing. *See* ECF 102 at 176–78, *quoted in* ECF 110 at 28.

More specifically, during the proceedings before the Office of the Special Master, petitioner relegated her fibromyalgia diagnosis to the sequela of GBS. Based upon this representation, the special master noted: "Because I have determined that Petitioner did not have GBS, I have not analyzed whether she developed fibromyalgia after and as a consequence of GBS." ECF 110 at 28. In her motion for review to this Court, petitioner maintains the same GBS-focused approach.[9] Although present during (and participating in) the virtual hearing before the special master, petitioner was not specifically asked to confirm on the record her agreement with her counsel's modified litigative approach.

To flesh out this issue, in advance of oral argument, the Court directed all counsel to be prepared to address the following: (1) the evolution of petitioner's initial fibromyalgia-based claim to the briefed and presented GBS-based claim; (2) whether petitioner was consulted and consented to the amended GBS-based claim in lieu of the fibromyalgia-based claim; and (3) whether the matter should be remanded to the Office of the Special Master to determine in the first instance whether the original claim of fibromyalgia is compensable under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et seq*.[10] In addressing these issues, the Court instructed counsel to be prepared to discuss the potential application of the Federal Circuit's recent decision in *DiMasi v. Secretary of Health & Human Services*, No. 22-1854, 2023 WL 4697122 (Fed. Cir. July 24, 2023), *pet'n for reh'g denied* (Sept. 12, 2023).

During oral argument conducted on September 13, 2023, petitioner's counsel thoughtfully explained the GBS-based claim–noted in the original petition–was deliberately and consistently presented throughout the proceedings before the Office of the Special Master. According to counsel, the deliberate litigation strategy was to use the subsequent fibromyalgia diagnosis and treatment as evidence of the initial GBS working diagnosis, which bore the necessary temporal relationship to the November 6, 2013 flu shot and, most significantly, explained petitioner's December 2013 symptoms. Counsel's representations are consistent with petitioner's expert

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[9] *See, e.g.*, ECF 111 at 1 ("[N]o alternative to GBS was established except Fibromyalgia, which is also consistent as following from GBS or being simply long-term effects of GBS."); *id.* at 9 ("The full medical record is fully consistent with a GBS diagnosis and nothing else."); *id.* at 9–10 ("[T]he GBS diagnosis is correct . . . . The diagnosis of Fibromyalgia is based on a different stage of the same injury."); *cf.* ECF 118 at 2 ("While the Petitioner's experts disagree whether Ms. Larson suffered from [GBS or fibromyalgia] or both, they opine that either GBS can lead to Fibromyalgia or that the symptoms deemed Fibromyalgia are the sequela of GBS. In either case, the injury is established.").

[10] Counsel were also advised the Court would inquire about the significance, if any, that petitioner never underwent immunotherapy to treat her claimed GBS. Petitioner's counsel downplayed the need for GBS-targeted treatment in light of the near-immediate improvement in petitioner's most severe symptoms (i.e., difficulty breathing, facial drooping); in turn, respondent's counsel included this item in the laundry list of disconnects from a typical GBS diagnosis. As noted in Section II, *supra*, the Court found this fact supportive of the decision below.

witness reports dating back to September 2017 and February 2018. *See* ECF 42-1; ECF 46-1. These representations are further consistent with the parties' pre- and post-hearing briefing before the Office of the Special Master as well as the motion for review pending before this Court. And, as detailed above, any conflation was clarified during the November 8, 2021 hearing before the special master. *See* ECF 102 at 176–78.

Turning to petitioner's consultation and consent to the amended claim, her counsel of record credibly stated: since taking over this case in May 2019, the theory of recovery consistently has been GBS-based with fibromyalgia as the sequela of GBS. Upon this premise, counsel explained no pointed conversation with petitioner about abandoning (or compromising) an independent fibromyalgia-based claim took place as it was unnecessary given the medical evidence presented and the consistent (longstanding) litigation strategy. On this point, it is worth noting petitioner attended (and participated in) the entire November 8, 2021 virtual hearing before the special master when the GBS-based claim was presented, and her counsel engaged in the exchange with the special master about the nature and scope of petitioner's claim. Further, review of petitioner's hearing testimony–which focused on her preliminary GBS diagnosis–supports finding petitioner was aware she was not pursuing a fibromyalgia-based claim. While it clearly would have been preferable for the special master to ask petitioner on the record if she both understood and agreed with her counsel's representations regarding the nature and scope of her claim, such process is not required. Readily distinguishable from *DiMasi*, the facts here do not present the rare case of gross misconduct from which petitioner should be excused from the tactical decisions of her chosen counsel. *See* 2023 WL 4697122, at *8–10 (gross misconduct claim substantiated where attorney abandoned significant aggravation claim without consulting client or seeking her consent and, thereafter, misrepresented the special master's decision dismissing the claim).

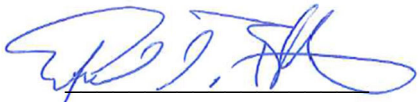
For these reasons, there is no basis in fact or in law to merit a remand to the Office of Special Master to determine in the first instance whether a standalone fibromyalgia-based claim could succeed.[11]

[11] To this point, it is worth noting: one of petitioner's expert witnesses opined petitioner's fibromyalgia evolved from the alleged GSB the special master found petitioner failed to establish, *see* ECF 102 at 80, 86–87, 89–90, 91–92, 105, 106–07; and petitioner's other expert maintained petitioner never contracted fibromyalgia related to her flu shot. *See id.* at 47, 61, 71.

CONCLUSION

For the foregoing reasons, the petitioner's motion for review (ECF 111) is **DENIED** and the decision of the special master (ECF 110) is **SUSTAINED**.

It is so **ORDERED**.



Armando O. Bonilla
Judge